

MEDI-10- acetylcysteine, levomefolate calcium, methylcobalamin, pyridoxal 5-phosphate, niacinamide, cholecalciferol, chromium picolinate, alpha lipoic acid, ubidecarenone and resveratrol capsule
Medicap laboratories Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

MEDI-10

Active Ingredients

Ingredients	Strength
Acetylcysteine	200 mg
Methyltetrahydrofolate(Vitamin B9)	2.5 mg
Methylcobalamin (Vitamin B12)	2.5 mg
Pyridoxal 5'-phosphate (Vitamin B6)	20 mg
Nicotinamide (Vitamin B3)	10 mg
Cholecalciferol (Vitamin D3)	1000 IU
Chromium Picolinate	1 mg
Alpha Lipoic Acid	200 mg
Coenzyme Q10	16 mg
Resveratrol	83 mg

Indication and Usage

Medi-10 capsule is an orally administered prescription dietary supplement specifically formulated for the dietary management of patients with unique nutritional needs where advanced folate supplementation is required or in management of endothelial dysfunction with diabetic peripheral neuropathy.

Medi-10 capsule can be prescribed as therapeutic nutritional supplementation in physiologically stressful conditions for maintenance of good health. It also supports healthy metabolism of glucose and carbohydrates.

Warnings and Precautions

Medi-10 capsules should be use only under the direction and supervision of a licensed physician.

This product is **contraindicated** in patients with a known hypersensitivity to any of the ingredients. Call your medical practitioner about side effects.

General:

Folates (including folic acid and reduced folates), when administered as a single agent in doses above 0.1 mg daily, may obscure the detection of B12 deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B12 deficiency, including pernicious anemia, while not addressing the neurological manifestations). Reduced folates may be less likely than folic acid to mask vitamin B12 deficiency. Folate therapy alone is inadequate for the treatment of B12 deficiency.

Folate Regulation

The term "folates" are B vitamins that include folic acid and any forms of active pteroylglutamates regardless of the reduction state of the molecule. Folates, or vitamin B9, are primarily hydrolyzed in

the intestinal jejunum and the liver to the active circulating form of folate, l-methylfolate, with an intermediate stable form, 5,10-methylenetetrahydrofolate.

Individuals with genetic polymorphisms for the genes coding methylenetetrahydrofolate reductase (MTHFR) may not be capable of utilizing or metabolizing folic acid adequately for the vitamin B12-dependent methylation cycle.

Folic acid, including reduced forms* such as folinic acid, may obscure pernicious anemia above 0.1 mg doses, and must be administered under the supervision of a licensed medical practitioner.

The 1971, 1972, 1973, 1980, 1984, 2000, and 2010 Federal Register Notices addressed this concern while establishing that increased folate was proper therapy in megaloblastic anemias - specifically where homocysteine levels were elevated or risk of neural tube defects (NTDs) was at issue.

The Federal Register Notice of August 2, 1973 (38 FR 20750) specifically states that: Dietary supplement preparations are available without a prescription (21 CFR 121.1134). Levels higher than dietary supplement amounts are available only with a prescription.

Folic acid - including reduced forms, may be added to medical foods undefined in section 5(b)(3) of the Orphan Drug Act (21 USC 360ee(b)(3)), or to food (21 CFR 172.345).

* It is not known whether or not l-methylfolate can obscure pernicious anemia above 0.1 mg doses, so caution is advised also with this form of folate.

Medi-10 capsule is not an antidepressant; however, folate has been shown to enhance antidepressant effects of known antidepressants. Caution is recommended in patients with a history of bipolar illness.

Drug Interactions:

Drug interactions with vitamin B6:

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

Drug interactions with folate:

- High dose folic acid may result in decreased serum levels for pyrimethamine and first-generation anticonvulsants (carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, valproic acid, valproate).
- Folic acid may decrease a patient's response to methotrexate.
- 5-formyltetrahydrofolate may increase the toxicity of Capecitabine.

Drug interactions with vitamin B12:

- Antibiotics, cholestyramine, colchicines, colestipol, metformin, para-aminosalicylic, and potassium chloride may decrease the absorption of vitamin B12.
- Nitrous oxide can produce a functional vitamin B12 deficiency.

Adverse Reactions:

Allergic sensitization has been reported following both oral and parental administration of folic acid, and may possibly occur with other forms of folate.

Allergic reactions have been reported following the use of oral and parenteral vitamin B9.

Nausea, vomiting, diarrhea, transient skin rash, flushing, epigastric pain, and constipation have been associated with acetylcysteine.

Paresthesia, somnolence, nausea and headaches have been reported with pyridoxal 5'-phosphate.

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

Ask Doctor/Pharmacist:

Talk to your healthcare practitioner and/or pharmacist before taking or using any prescription or over-the-counter medicines or herbal/health supplements alongside this product.

Pregnancy or Breast feeding:

Medi-10 capsule is not intended for use as a prenatal/postnatal multivitamin for lactating and non-lactating mothers.

This product contains a B vitamin in reduced form. Talk with your medical practitioner before using if pregnant or lactating.

Keep out of reach of children:

Keep this out of the reach of children.

This product is not recommended for use in children under the age of twelve.

Dosage and Administration

Usual adult dose is one capsule once or twice in a day or as prescribed by licensed medical practitioner.

How supplied: 60 capsules dispensed in amber color bottle.

Storage and Handling

Store at controlled room temperature 20°C to 25°C (68°F to 77°F).

Protect from light and moisture. Dispense in a tight, light-resistant container.

Questions?

Call us at 800-494-7449

PRINCIPAL DISPLAY PANEL

ACTIVE INGREDIENTS Each capsule contains the following dietary ingredients: Acetylcysteine200 mg Methyltetrahydrofolate2.5 mg Methylcobalamin2.5 mg Pyridoxal 5'-phosphate20 mg Nicotinamide10 mg Cholecalciferol1000 IU Chromium Picolinate1 mg Alpha Lipic Acid200 mg Coenzyme 1016 mg Resveratrol83 mg	Rx Only NDC # 69589-004-06  MEDI-10 Prescription Dietary Supplement 60 Capsules	Pregnancy of breast feeding Medi-10 capsule is not intended for use as a prenatal/postnatal multivitamin for lactating and non-lactating mothers. This product contains a B vitamin in reduced form. Talk with your medical practitioner before using if pregnant or lactating. Keep out of reach of children Keep this out of the reach of children. This product is not recommended for use in children under the age of twelve. DOSAGE AND ADMINISTRATION Usual adult dose is one capsule once or twice in a day or as prescribed by a licensed medical practitioner. How Supplied: 60 capsules dispensed in amber color bottle. STORAGE AND HANDLING Store at controlled room temperature 20°C to 25°C (68°F to 77°F). Protect from light and moisture. Dispense in a tight, light-resistant container. QUESTIONS ? call us at 800-494-7449 Rev.01
INDICATION AND USAGE Medi-10 capsule is an orally administered prescription dietary supplement specifically formulated for the dietary management of patients with unique nutritional needs where advanced folate supplementation is required or in management of endothelial dysfunction with diabetic peripheral neuropathy. Medi-10 capsule can be prescribed as therapeutic nutritional supplementation in physiologically stressful conditions for maintenance of good health. It also supports healthy metabolism of glucose and carbohydrates. WARNINGS AND PRECAUTION Medi-10 capsules should be used only under the direction and supervision of a licensed physician. This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Call your medical practitioner about side effects. Ask Doctor/Pharmacist Talk to your healthcare practitioner and/or pharmacist before taking or using any prescription or over-the-counter medicines or herbal/health supplements alongside this product.	Distributed by: Medicap laboratories Inc. 125 Country Club Drive, Suite A, Tampa, FL, 33612 Made in Canada	Lot # Exp date:  3 69589 00406 0

MEDI-10

acetylcysteine, methyltetrahydrofolate, methylcobalamin, pyridoxal 5-phosphate, nicotinamide, cholecalciferol,

chromium picolinate, alpha lipoic acid, coenzyme 10 and resveratrol capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69589-004
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetylcysteine (UNII: WYQ7N0BPYC) (ACETYLCYSTEINE - UNII:WYQ7N0BPYC)	Acetylcysteine	200 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	2.5 mg
Methylcobalamin (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	Methylcobalamin	2.5 mg
PYRIDOXAL 5-PHOSPHATE (UNII: F06SGE49M6) (PYRIDOXAL 5-PHOSPHATE - UNII:F06SGE49M6)	PYRIDOXAL 5-PHOSPHATE	20 mg
niacinamide (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	niacinamide	10 mg
Cholecalciferol (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	Cholecalciferol	1000 [iU]
Chromium Picolinate (UNII: S71T8B8Z6P) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIC CATION	1 mg
Alpha Lipoic Acid (UNII: 73Y7P0K73Y) (.ALPHA.-LIPOIC ACID - UNII:73Y7P0K73Y)	Alpha Lipoic Acid	200 mg
UBIDECARENONE (UNII: EJ27X76M46) (UBIDECARENONE - UNII:EJ27X76M46)	UBIDECARENONE	16 mg
RESVERATROL (UNII: Q369O8926L) (RESVERATROL - UNII:Q369O8926L)	RESVERATROL	83 mg

Product Characteristics

Color	purple	Score	no score
Shape	capsule	Size	24mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69589-004-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2015	

Labeler - Medicap laboratories Inc. (078798864)

Establishment

Name	Address	ID/FEI	Business Operations
Medicap laboratories Inc.		078798864	wholesale drug distributor(69589-004)

